IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC, BESINS HEALTHCARE INC., and LABORATOIRES BESINS INTERNATIONAL, SAS, Plaintiffs, v. PERRIGO COMPANY and PERRIGO ISRAEL PHARMACEUTICALS LTD., Defendants.	)	C.A. No. 13-236 (RGA) (Consolidated)
UNIMED PHARMACEUTICALS, LLC, BESINS HEALTHCARE INC., and LABORATOIRES BESINS INTERNATIONAL, SAS, Plaintiffs, v. WATSON LABORATORIES, INC. and ACTAVIS, INC., Defendants.	)	

PLAINTIFFS' ANSWER TO DEFENDANT PERRIGO ISRAEL PHARMACEUTICALS LTD.'S COUNTERCLAIMS

Plaintiffs Unimed Pharmaceuticals, LLC ("Unimed"), Besins Healthcare Inc. ("Besins Healthcare"), and Laboratoires Besins International, SAS ("Laboratoires Besins") (collectively "Plaintiffs"), by and through their undersigned attorneys, respond to the Counterclaims of Defendant Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo Israel") as follows:

COUNTERCLAIMS

PARTIES

1. On information and belief, Unimed Pharmaceuticals, LLC ("Unimed"), purports to be a corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. On information and belief, Unimed purports to be a subsidiary of AbbVie Inc. ("AbbVie").

RESPONSE: Admitted.

2. On information and belief, Besins Healthcare Inc. ("Besins Healthcare") purports to be a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 607 Herndon Parkway, Suite 210, Herndon, Virginia 20170.

RESPONSE: Admitted.

3. On information and belief, Laboratoires Besins International, SAS ("Laboratoires Besins") purports to be a French company, with its principal place of business at 3 Rue Du Bourg L'Abbe, Paris, France 75003.

RESPONSE: Admitted.

4. Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo Israel") is a company organized and existing under the laws of Israel having a principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

RESPONSE: On information and belief, admitted.

JURISDICTION AND VENUE

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.;* the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

RESPONSE: Plaintiffs admit that Perrigo Israel purports to bring these Counterclaims under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.; the Declaratory Judgment Act,

28 U.S.C. §§ 2201 and 2202; and the MMA, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5), but deny that the Counterclaims have any merit.

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

RESPONSE: The allegations in paragraph 6 constitute conclusions of law and therefore do not require a response. To the extent that a response is required, Plaintiffs do not contest the Court's subject matter jurisdiction over these Counterclaims.

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants Unimed, Besins Healthcare, and Laboratoires Besins at least because Unimed, Besins Healthcare, and Laboratoires Besins availed themselves of the rights and privileges of this forum by suing Perrigo Israel in this District, and, on information and belief, because Plaintiffs/Counterclaim-Defendants Unimed, Besins Healthcare, and Laboratoires Besins conduct substantial business in, and have regular systematic contact with, this District.

RESPONSE: The allegations in paragraph 7 constitute conclusions of law and therefore do not require a response. To the extent that a response is required, Plaintiffs admit that they filed the instant action against Perrigo Israel and its parent, Perrigo Company, for patent infringement under the Hatch-Waxman Act. Further answering, Plaintiffs do not contest the Court's exercise of personal jurisdiction over Plaintiffs for the purpose of this action, including adjudication of the Counterclaims. Plaintiffs deny all remaining allegations in paragraph 7.

8. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

RESPONSE: The allegations in paragraph 8 constitute conclusions of law and therefore do not require a response. To the extent a response is required, Plaintiffs admit that venue is proper in this District for the purpose of this action, including adjudication of the Counterclaims.

BACKGROUND

A. FDA Approval of New Brand-Name Drugs.

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417,98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the MMA, sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

RESPONSE: The allegations in paragraph 9 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the FFDCA is the best source for its requirements.

10. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA'') for consideration by FDA. *See* 21 U.S.C. § 355.

RESPONSE: The allegations in paragraph 10 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the FFDCA is the best source for its requirements.

11. An NDA includes, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(l), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

RESPONSE: The allegations in paragraph 11 constitute conclusions of law regarding the requirements of federal statutes and regulations, and therefore do not require a response. The text of the laws and regulations is the best source for their requirements.

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

RESPONSE: The allegations in paragraph 12 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the statute is the best source for its requirements

B. Generic Competition- Abbreviated New Drug Applications ("ANDAs").

13. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA'').

RESPONSE: The allegations in paragraph 13 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the FFDCA is the best source for its requirements.

14. To receive approval of its ANDA, the statute requires an applicant to, *inter alia,* show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(J)(4)(F).

RESPONSE: The allegations in paragraph 14 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the statute is the best source for its requirements.

15. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must, generally speaking, "certify" to any patent information listed in the Orange Book. *See* 21 U.S.C. § 355(J)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

RESPONSE: The allegations in paragraph 15 constitute conclusions of law regarding the requirements of a federal statute and regulation, and therefore do not require a response. The text of the laws is the best source for their requirements.

16. When seeking FDA approval to market prior to patent expiration, an ANDA applicant must, generally speaking, submit a so-called "paragraph IV" certification asserting

that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(J)(2)(A)(vii)(IV).

RESPONSE: The allegations in paragraph 16 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the statute is the best source for its requirements.

17. An applicant submitting an ANDA containing a paragraph IV certification must notify both the purported patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(J)(2)(B).

RESPONSE: The allegations in paragraph 17 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the statute is the best source for its requirements.

18. With respect to a patent, the information for which was submitted to FDA prior to ANDA filing, if the patent holder brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(J)(2)(B), FDA cannot approve the ANDA for 30 months, unless the district court enters an order shortening that period. *See* 21 U.S.C. § 355(J)(5)(B)(iii). For this reason alone, patentees and NDA holders have a significant financial incentive to bring an infringement suit against an ANDA applicant regardless of the merit-- or lack thereof -- of that infringement suit.

RESPONSE: The allegations in the first sentence of paragraph 18 constitute conclusions of law regarding the requirements of a federal statute, and therefore do not require a response. The text of the statute is the best source for its requirements. Plaintiffs deny all remaining allegations in paragraph 18.

C. AndroGel® (Testosterone Gel), 1.62% And The Patents-In-Suit.

19. On or about January 7, 2003, according to the electronic records of the U.S. Patent and Trademark Office ("USPTO"), U.S. Patent No. 6,503,894 B1 ("the '894 patent"), entitled "PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING HYPOGONADISM" issued, on its face, to inventors Robert E. Dudley, S. George Kottayil, and Olivier Palatchi, and was assigned, on its face, to Unimed Pharmaceuticals, Inc. and Laboratories Besins Iscovesco. Unimed and Besins Healthcare purport to be the owners of all right, title and interest in the '894 patent. On information and belief, a true and correct copy of the '894 patent is attached hereto as Exhibit A.

RESPONSE: Plaintiffs admit that the '894 patent on its face lists Robert E. Dudley, S. George Kottayil, and Olivier Palatchi as the inventors. Further answering, the list of inventors was corrected on or about May 22, 2007 via a Certificate of Correction, to clarify that the inventors are Robert E. Dudley and Dominique Drouin. Plaintiffs admit the remaining allegations in paragraph 19, including that Exhibit A purports to be a true and correct copy of the '894 patent.

20. On or about June 18, 2013, according to the electronic records of the USPTO, U.S. Patent No. 8,466,136 B2 ("the '136 patent"), entitled "TESTOSTERONE GEL AND METHOD OF USE" issued, on its face, to inventors Ramana Malladi and Jodi Stahlman, and was assigned, on its face, to Unimed Pharmaceuticals, LLC and Laboratoires Besins International, SAS. Unimed and Laboratoires Besins purport to be the owners of all right, title and interest in the '136 patent. On information and belief, a true and correct copy of the '136 patent is attached hereto as Exhibit B.

RESPONSE: Admitted.

21. On or about June 18, 2013, according to the electronic records of the USPTO, U.S. Patent No. 8,466,137 B2 ("the '137 patent"), entitled "TESTOSTERONE GEL AND METHOD OF USE" issued, on its face, to inventors Ramana Malladi and Jodi Stahlman, and was assigned, on its face, to Unimed Pharmaceuticals, LLC and Laboratoires Besins International, SAS. Unimed and Laboratoires Besins purport to be the owners of all right, title and interest in the '137 patent. On information and belief, a true and correct copy of the '137 patent is attached hereto as Exhibit C.

RESPONSE: Admitted.

22. On or about June 18, 2013, according to the electronic records of the USPTO, U.S. Patent No. 8,466,138 B2 ("the '138 patent"), entitled "TESTOSTERONE GEL AND METHOD OF USE" issued, on its face, to inventors Ramana Malladi and Jodi Miller, and was assigned, on its face, to Unimed Pharmaceuticals, LLC and Laboratoires Besins International, SAS. Unimed and Laboratoires Besins purport to be the owners of all right, title and interest in the '138 patent. On information and belief a true and correct copy of the '138 patent is attached hereto as Exhibit D.

RESPONSE: Admitted

23. On or about July 16, 2013, according to the electronic records of the USPTO, U.S. Patent No. 8,486,925 B2 ("the '925 patent"), entitled "TESTOSTERONE GEL AND METHOD OF USE" issued, on its face, to inventors Ramana Malladi and Jodi Miller, and was assigned, on its face, to Unimed Pharmaceuticals, LLC and Laboratoires Besins International, SAS. Unimed and Laboratoires Besins purport to be the owners of all right, title and interest in the '925 patent. On information and belief, a true and correct copy of the '925 patent is attached hereto as Exhibit E.

RESPONSE: Admitted.

24. On information and belief, and according to the online FDA records, AbbVie Inc. currently holds approved NDA No. 22-309 for AndroGel® (Testosterone Gel), 1.62%.

RESPONSE: Admitted.

25. On information and belief, information on the '894, '136, '137, '138, and '925 patents was submitted to FDA for listing in the Orange Book. By virtue of that submission, FDA listed the '894, '136, '137, '138, and '925 patents in the Orange Book in connection with the approved NDA No. 22-309 for AndroGel® (Testosterone Gel), 1.62%.

RESPONSE: Plaintiffs admit that the '894, '136, '137, '138, and '925 patents are properly listed in the Orange Book in connection with the approved NDA No. 22-309 for AndroGel® (Testosterone Gel), 1.62%. Plaintiffs deny all other allegations in Paragraph 25.

D. Perrigo Israel's Testosterone Gel, 1.62% ANDA.

26. Perrigo Israel filed an ANDA with the FDA seeking approval for Testosterone Gel, 1.62%. FDA assigned Perrigo Israel's ANDA No. 204268.

RESPONSE: Plaintiffs admit that Perrigo Company, as agent for Perrigo Israel, filed an ANDA with the FDA seeking approval for Testosterone Gel, 1.62% and that FDA assigned that ANDA as No. 204268. Plaintiffs deny all other allegations in paragraph 26.

27. Perrigo Israel's ANDA references NDA No. 22-309.

RESPONSE: Plaintiffs admit that ANDA No. 204268 references NDA No. 22-309. Plaintiffs deny all other allegations in paragraph 27.

28. Perrigo Israel submitted its ANDA with a paragraph IV certification to the '894 patent.

RESPONSE: Plaintiffs admit that ANDA No. 204268 includes a paragraph IV certification to the '894 patent. Plaintiffs deny all other allegations in paragraph 28.

29. Perrigo Israel amended its ANDA to contain a paragraph IV certification to the '136, '137, '138, and '925 patents.

RESPONSE: Plaintiffs admit that ANDA No. 204268 was amended to include a paragraph IV certification to the '136, '137, '138, and '925 patents. Plaintiffs deny all other allegations in paragraph 29.

30. Because Perrigo Israel's ANDA seeks FDA approval to market its generic Testosterone Gel, 1.62% product before expiration of the Orange Book-listed '894, '136, '137, '138, and '925 patents, Perrigo Israel's ANDA currently includes a paragraph IV certification to the '894, '136, '137, '138, and '925 patents.

RESPONSE: Plaintiffs admit that ANDA No. 204268 seeks FDA approval to market Defendants' infringing generic Testosterone Gel, 1.62% product before expiration of the Orange Book-listed '894, '136, '137, '138, and '925 patents, and that the ANDA includes a paragraph IV certification directed to the '894, '136, '137, '138, and '925 patents. Plaintiffs deny all other allegations in paragraph 30.

31. In accordance with 21 U.S.C. § 355(J)(2)(B), Perrigo Israel provided, *inter alia*, Unimed and Besins Healthcare with notice that Perrigo Israel submitted an ANDA containing a paragraph IV certification to the '894 patent (hereinafter, "Perrigo Israel's First Notice Letter"). Perrigo Israel's First Notice Letter included a detailed statement setting forth factual and legal bases as to why the '894 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA, and *inter alia*, expressly reserved the right to raise additional defenses (including, but not limited to, defenses specific to inventorship and patent unenforceability due to inequitable conduct before the USPTO) in the event that suit was filed on the '894 patent.

RESPONSE: Plaintiffs admit that Defendants provided a Notice Letter to Unimed and Besins Healthcare notifying them that Defendants submitted an ANDA containing a paragraph IV certification to the '894 patent ("Defendants' First Notice Letter"). Plaintiffs further admit that the Defendants' First Notice Letter included a statement setting forth certain arguments by Perrigo Israel and Perrigo Company as to why they believe the '894 patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Testosterone Gel, 1.62% product described in Defendants' ANDA. Plaintiffs deny that the '894 patent is invalid, unenforceable and/or will not be infringed. Plaintiffs further deny that Defendants can reserve the right to raise any additional defenses or theories that were not disclosed in Defendants' First Notice Letter. Federal law requires that Defendants' First Notice Letter set forth "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed," *see* 21 U.S.C § 355(j)(2)(B)(iv), including a "full and detailed explanation of why the claim is not infringed" and a "full and detailed explanation of the ground supporting" any allegation that the claims of the listed patent are invalid or unenforceable, *see* 21 C.F.R. § 314.95(c)(6)(i) - (ii). Plaintiffs deny all other allegations in paragraph 31.

32. In accordance with 21 U.S.C. § 355(J)(2)(B), Perrigo Israel provided, *inter alia*, Unimed and Laboratoires Besins with notice that Perrigo Israel amended its ANDA No. 204268 to contain a paragraph IV certification to the '136, '137, '138, and '925 patents (hereinafter, "Perrigo Israel's Second Notice Letter"). Perrigo Israel's Second Notice Letter included a detailed statement setting forth factual and legal bases as to why the '136, '137, '138, and '925 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA, and *inter alia*, expressly reserved the right to raise additional defenses (including, but not limited to, defenses specific to inventorship and patent unenforceability due to inequitable conduct before the USPTO) in the event that suit was filed on the '136, '137, '138, and '925 patents.

RESPONSE: Plaintiffs admit that Defendants provided a Notice Letter to Unimed and Laboratoires Besins notifying them that Defendants submitted had amended ANDA No. 204268 to include a paragraph IV certification to the '136, '137, '138, and '925 patents ("Defendants' Second Notice Letter"). Plaintiffs further admit that the Defendants' Second Notice Letter included a statement setting forth certain arguments by Perrigo Israel and Perrigo Company as to why they believe the '136, '137, '138, and '925 patents are invalid and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Testosterone Gel, 1.62% product described in Defendants' ANDA. Plaintiffs deny that the '136, '137, '138, and '925 patents are invalid, unenforceable and/or will not be infringed. Plaintiffs further deny that Defendants can reserve the right to raise any additional defenses or theories that were not disclosed in Defendants' Second Notice Letter. Federal law requires that Defendants' Second Notice Letter set forth "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed," *see* 21 U.S.C § 355(j)(2)(B)(iv), including a "full and detailed explanation of why the claim is not infringed" and a "full and detailed explanation of the ground supporting" any allegation that the claims of the listed patents are invalid or unenforceable, *see* 21 C.F.R. § 314.95(c)(6)(i) - (ii). Plaintiffs deny all other allegations in paragraph 32.

33. Unimed and Besins Healthcare brought suit against Perrigo on or about February 15, 2013. Plaintiffs filed a First Amended Complaint against Perrigo on or about October 8, 2013.

RESPONSE: Admitted.

34. Plaintiffs' suit against Perrigo Co. and Perrigo Israel on the '894 patent is objectively baseless, sham litigation brought for the improper purpose of, *inter alia*, obtaining a 30-month stay of FDA's approval of Perrigo Israel's ANDA product and interfering with Perrigo Israel's ability to market its competing product.

RESPONSE: Denied.

35. The Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA does not infringe any claim of the '894 patent.

RESPONSE: Denied.

36. The claims of the '894 patent are invalid.

RESPONSE: Denied.

37. The '894 patent is unenforceable due, at the very least, to patent misuse for at least the reasons detailed herein.

RESPONSE: Denied.

38. The Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA does not infringe any valid and enforceable claim of the '136 patent.

RESPONSE: Denied.

39. The claims of the '136 patent are invalid.

RESPONSE: Denied.

40. The Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA does not infringe any valid and enforceable claim of the '137 patent.

RESPONSE: Denied.

41. The claims of the '137 patent are invalid.

RESPONSE: Denied.

42. The Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA does not infringe any valid and enforceable claim of the '138 patent.

RESPONSE: Denied.

43. The claims of the '138 patent are invalid.

RESPONSE: Denied.

44. The Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA does not infringe any valid and enforceable claim of the '925 patent.

RESPONSE: Denied.

45. The claims of the '925 patent are invalid.

RESPONSE: Denied.

E. Unimed and Besins Healthcare Have No Reasonable Expectation Of Success On the Merits Of Any Infringement Claim Relating To The '894 Patent.

46. Unimed and Besins Healthcare are aware, *inter alia*, that the '894 patent is invalid as a result, *inter alia*, of the facts set forth in Perrigo Israel's First Notice Letter and facts made known to Unimed and Besins Healthcare during earlier litigation against other ANDA applicants involving the '894 patent. *See, e.g., Unimed Pharm., Inc. et al. v. Watson Pharm., Inc.*, No. 1:03-CV-2501-TWT (N.D. Ga.); *Unimed Pharm., Inc. et al. v. Paddock Labs., Inc.*, No. 1:03-CV-2503-TWT (N.D. Ga.); *Abbott Prods., Inc. et al. v. Teva Pharm. USA, Inc.*, No. 1:11-cv-384-HB (D. Del.). All such cases asserting the '894 patent shall be referred to collectively herein as "Prior '894 Patent Cases."

RESPONSE: Denied. In *In re: Androgel Antitrust Litigation* (No. II), 888 F. Supp. 2d 1336 (N.D. Ga. 2012), the district court addressed multiple invalidity challenges to the '894 patent (including many of the same arguments advanced here by Perrigo) and rejected the defendants' request for judgment as a matter of law that the '894 patent was invalid. Importantly, the district court also held that the assertion of the '894 patent in *Unimed Pharm., Inc. et al. v. Watson Pharm., Inc.*, No. 1:03-CV-2501-TWT (N.D. Ga.), and *Unimed Pharm., Inc. et al. v. Paddock Labs., Inc.*, No. 1:03-CV-2503-TWT (N.D. Ga.), was not objectively baseless. Additionally, in not only the Prior '894 Patent Cases identified by Defendants, but also *Abbott Products, Inc. v. Perrigo Company*, No. 3:11-cv-6357 (D.N.J.), which similarly involved the '894 patent, the parties, including Perrigo Company and Perrigo Israel, resolved the respective infringement disputes by entering into arms-length settlement agreements.

47. Unimed and Besins Healthcare are aware, *inter alia*, that Perrigo Israel's ANDA product does not infringe the '894 patent as a result, *inter alia*, of the facts set forth in Perrigo Israel's First Notice Letter and the ANDA documents that Perrigo Israel provided pre-suit to, *inter alia*, counsel for Unimed.

RESPONSE: Denied.

48. By purporting to bring this lawsuit within 45 days of receiving Perrigo Israel's First Notice Letter, Unimed and Besins Healthcare claim to have triggered a 30-month stay of FDA approval of Perrigo Israel's ANDA, thereby improperly delaying the sale of the product described in that ANDA.

RESPONSE: Plaintiffs admit only that, because Unimed and Besins Healthcare properly initiated this lawsuit within 45 days of receiving Defendants' First Notice Letter, a 30-month stay on FDA approval of the ANDA is now in place by operation of federal statute. 21 U.S.C. §355. Plaintiffs deny all other allegations in paragraph 48.

49. Unimed and Besins Healthcare are attempting to enforce the '894 patent in bad faith and for the improper purpose of *inter alia*, keeping Perrigo Israel's ANDA product off the competitive marketplace for at least 30 months.

RESPONSE: Denied.

50. Unimed's and Besins Healthcare's actions in, *inter alia*, maintaining the '894 patent in the Orange Book and asserting the '894 patent against Perrigo Israel (despite knowing that patent, *inter alia*, to be invalid and not infringed) have, according to Unimed and Besins Healthcare, resulted in a 30-month stay of the approval of Perrigo Israel's ANDA. By their acts of misuse, Unimed and Besins Healthcare have impermissibly broadened the scope of the '894 patent with anti-competitive effect.

RESPONSE: Plaintiffs admit only that, because Unimed and Besins Healthcare properly initiated this lawsuit within 45 days of receiving Defendants' First Notice Letter, a 30-month stay on FDA approval of the ANDA is now in place by operation of federal statute. 21 U.S.C. § 355. Plaintiffs deny all other allegations in paragraph 50.

51. Unimed and Besins Healthcare have no realistic expectation of success on the merits in bringing the present lawsuit, as at least the '894 patent is invalid and not infringed.

RESPONSE: Denied.

52. Unimed's and Besins Healthcare's lawsuit is objectively baseless because, at the very least, based upon the information in Perrigo Israel's First Notice Letter, the ANDA documents that Perrigo Israel provided pre-suit to, *inter alia*, counsel for Unimed, and facts made known to Unimed and Besins Healthcare during Prior '894 Patent Cases, Unimed and Besins Healthcare knew or should have known that the '894 patent is invalid and not infringed.

RESPONSE: Denied.

COUNTERCLAIM I:
DECLARATION OF NON-INFRINGEMENT OF THE '894 PATENT

53. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-52.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-52 of the Counterclaims as if fully set forth herein.

54. A present, genuine, and justiciable controversy exists between Unimed and Besins Healthcare and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would infringe the claims of the '894 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Besins Healthcare and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Defendants' ANDA would infringe the claims of the '894 patent. Plaintiffs deny all other allegations in paragraph 54.

55. The manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe the claims of the '894 patent.

RESPONSE: Denied.

56. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe the claims of the '894 patent.

RESPONSE: Denied.

COUNTERCLAIM II:
DECLARATION OF INVALIDITY OF THE '894 PATENT

57. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-56.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-56 of the Counterclaims as if fully set forth herein.

58. A present, genuine, and justiciable controversy exists between Unimed and Besins Healthcare and Perrigo Israel regarding, *inter alia*, the invalidity of the '894 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Besins Healthcare and Perrigo Israel regarding, *inter alia*, whether Perrigo Israel can prove, by clear and convincing evidence, that the '894 patent is invalid. Plaintiffs deny all other allegations in paragraph 58.

59. The claims of the '894 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

60. Perrigo Israel is entitled to a declaration that the '894 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

COUNTERCLAIM III:
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '894 PATENT: PATENT MISUSE

61. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-60.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-60 of the Counterclaims as if fully set forth herein.

62. Unimed's and Besins Healthcare's acts of misuse include bringing this lawsuit in bad faith with the knowledge, *inter alia*, that the '894 patent is invalid (and not infringed by Perrigo Israel's ANDA product) in order to stay Perrigo Israel's entry into the market.

RESPONSE: Denied.

63. Unimed's and Besins Healthcare's intention was to use this lawsuit against Perrigo Israel (and the resultant 30-month stay of approval), rather than the outcome of the lawsuit, to forestall, frustrate and prevent competition in the relevant market.

RESPONSE: Denied.

64. By its acts of misuse, Unimed and Besins Healthcare have used the '894 patent to restrain competition, even though the '894 patent is, *inter alia*, invalid (and not infringed by Perrigo Israel's ANDA product), for an additional 30 months.

RESPONSE: Denied.

65. By its acts of misuse, Unimed and Besins Healthcare have impermissibly broadened the scope of the '894 patent with anti-competitive effect.

RESPONSE: Denied.

66. Unimed's and Besins Healthcare's acts of misuse were done in bad faith and with the knowledge that the '894 patent is invalid (and not infringed by Perrigo Israel's ANDA product).

RESPONSE: Denied.

67. The '894 patent is unenforceable as a result of Unimed's and Besins Healthcare's misuse of that patent.

RESPONSE: Denied.

68. Perrigo Israel is entitled to a declaration that the '894 patent is unenforceable.

RESPONSE: Denied.

COUNTERCLAIM IV:
DECLARATION OF NON-INFRINGEMENT OF THE '136 PATENT

69. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-68.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-68 of the Counterclaims as if fully set forth herein.

70. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would infringe the claims of the '136 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Defendants' ANDA would infringe the claims of the '136 patent. Plaintiffs deny all other allegations in paragraph 70.

71. The manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '136 patent.

RESPONSE: Denied.

72. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '136 patent.

RESPONSE: Denied.

COUNTERCLAIM V:
DECLARATION OF INVALIDITY OF THE '136 PATENT

73. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-72.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-72 of the Counterclaims as if fully set forth herein.

74. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia,* the invalidity of the '136 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, whether Perrigo Israel can prove, by clear and convincing evidence, that the '136 patent is invalid. Plaintiffs deny all other allegations in paragraph 74.

75. The claims of the '136 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

76. Perrigo Israel is entitled to a declaration that the '136 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

COUNTERCLAIM VI:
DECLARATION OF NON-INFRINGEMENT OF THE '137 PATENT

77. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs l-76.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-76 of the Counterclaims as if fully set forth herein.

78. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would infringe the claims of the '137 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of

whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Defendants' ANDA would infringe the claims of the '137 patent. Plaintiffs deny all other allegations in paragraph 78.

79. The manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '137 patent.

RESPONSE: Denied.

80. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '137 patent.

RESPONSE: Denied.

COUNTERCLAIM VII:
DECLARATION OF INVALIDITY OF THE '137 PATENT

81. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-80.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-80 of the Counterclaims as if fully set forth herein.

82. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the invalidity of the '137 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, whether Perrigo Israel can prove, by clear and convincing evidence, that the '137 patent is invalid. Plaintiffs deny all other allegations in paragraph 82.

83. The claims of the '137 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

84. Perrigo Israel is entitled to a declaration that the '137 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

COUNTERCLAIM VIII:
DECLARATION OF NON-INFRINGEMENT OF THE '138 PATENT

85. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-84.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-84 of the Counterclaims as if fully set forth herein.

86. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would infringe the claims of the '138 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Defendants' ANDA would infringe the claims of the '138 patent. Plaintiffs deny all other allegations in paragraph 86.

87. The manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '138 patent.

RESPONSE: Denied.

88. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '138 patent.

RESPONSE: Denied.

COUNTERCLAIM IX:
DECLARATION OF INVALIDITY OF THE '138 PATENT

89. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs l-88.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-88 of the Counterclaims as if fully set forth herein.

90. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the invalidity of the '138 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, whether Perrigo Israel can prove, by clear and convincing evidence, that the '138 patent is invalid. Plaintiffs deny all other allegations in paragraph 90.

91. The claims of the '138 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

92. Perrigo Israel is entitled to a declaration that the '138 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

COUNTERCLAIM X:
DECLARATION OF NON-INFRINGEMENT OF THE '925 PATENT

93. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-92.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-92 of the Counterclaims as if fully set forth herein.

94. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of whether the

manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would infringe the claims of the '925 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Defendants' ANDA would infringe the claims of the '925 patent. Plaintiffs deny all other allegations in paragraph 94.

95. The manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '925 patent.

RESPONSE: Denied.

96. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, or sale of the Testosterone Gel, 1.62% product described in Perrigo Israel's ANDA would not infringe any valid and enforceable claim of the '925 patent.

RESPONSE: Denied.

COUNTERCLAIM XI:
Declaration of Invalidity of the '925 Patent

97. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-96.

RESPONSE: Plaintiffs incorporate by reference each of their above responses to paragraphs 1-96 of the Counterclaims as if fully set forth herein.

98. A present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, the invalidity of the '925 patent.

RESPONSE: Plaintiffs admit that a present, genuine, and justiciable controversy exists between Unimed and Laboratoires Besins and Perrigo Israel regarding, *inter alia*, whether

Perrigo Israel can prove, by clear and convincing evidence, that the '925 patent is invalid. Plaintiffs deny all other allegations in paragraph 98.

99. The claims of the '925 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

100. Perrigo Israel is entitled to a declaration that the '925 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

RESPONSE: Denied.

GENERAL DENIAL

Plaintiffs hereby deny all allegations in Perrigo Israel's Counterclaims that are not specifically admitted above.

RESPONSE TO PERRIGO ISRAEL'S REQUEST FOR RELIEF

Plaintiffs deny that Perrigo Israel is entitled to the judgment it seeks in paragraphs (a)-(n) of its Request for Relief. Perrigo Israel's Counterclaims for declaratory judgment of non-infringement and invalidity of the '894, '136, '137, '138, and '925 patents and unenforceability for patent misuse as to the **'**894 patent should be dismissed because the '894, '136, '137, '138, and '925 patents are valid and enforceable; and Perrigo Company and Perrigo Israel have been, are, or will be infringing one or more claims of the '894, '136, '137, '138, and '925 patents, as set forth in more detail in Plaintiffs' First Amended Complaint. For the same reasons, Perrigo Israel's demand for attorneys' fees and costs pursuant to 35 U.S.C. § 285 should be denied in its entirety, with prejudice.

SEPARATE ADDITIONAL DEFENSES

Plaintiffs allege the following separate and distinct additional defenses to Perrigo Israel's Counterclaims:

First Additional Defense

A. Counterclaim III (Patent Misuse) fails to state a claim against Plaintiffs upon which relief can be granted.

Second Additional Defense

B. Counterclaim III (Patent Misuse) is barred, in whole or in part, because Plaintiffs' conduct is protected under the *Noerr-Pennington* doctrine and under the Constitution of the United States.

Third Additional Defense

C. Counterclaim III (Patent Misuse) is barred because Perrigo Israel is equitably estopped from pursuing this claim against Plaintiffs.

Fourth Additional Defense

D. Plaintiffs reserve the right to assert additional affirmative defenses during or upon completion of discovery.

PRAYER FOR RELIEF

WHEREFORE, in addition to the relief prayed for in the Complaint, Plaintiffs pray for judgment as follows:

A. For an order dismissing Perrigo Israel's Counterclaims in their entirety with prejudice and denying all relief requested by Perrigo Israel;

B. For an order entering judgment on behalf of Unimed and Besins Healthcare on each of Perrigo Israel's Counterclaims concerning the '894 patent;

C. For an order entering judgment on behalf of Unimed and Laboratoires Besins on each of Perrigo Israel's Counterclaims concerning the '136, '137, '138, and '925 patents;

D. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or importation into the United States by Defendants of their proposed generic version of AndroGel® 1.62% would infringe the '894, '136, '137, '138, and '925 patents;

E. For a declaration that the '894, '136, '137, '138, and '925 patents are valid and enforceable; and

F. For such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Stephen J. Kraftschik

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